

**REPORT OF THE INTERAGENCY JOINT LABOR/MANAGEMENT  
COMMITTEE ON PRESCRIPTION DRUGS FROM CANADA**

**April 2004**

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## 1. Background

On November 4, 2003 the Montgomery County Council approved Resolution No. 15-385 on securing lower-price prescription drugs for current and retired employees of County agencies. (See circles 1-2.) The resolution discussed the impact of the soaring price of prescription drugs and the arguments for and against enabling active employees and retirees to obtain these drugs from Canada. The Canadian government sets price controls for prescription drugs that makes them significantly cheaper than the same drugs in the U.S. The resolution further called on the Task Force on Health Benefits Improvements, created on April 29, 2003 by then-Council President Michael Subin and chaired by Wendell M. Holloway, to examine this issue and report to the Council and the Management and Fiscal Policy Committee.

The Holloway Task Force, in its report to the Council dated November 25, 2003, proposed the creation of an interagency joint labor/management committee to pursue this effort. The report language, including the proposed charge to the Committee, is on circles 3-4.

The Committee, composed chiefly of County agency benefits experts and union representatives, was convened by Council Vice President Tom Perez. The committee met on January 9 and 21, February 4 and 19, and March 25, 2004.

The agency benefits experts – who provided valuable data and insights but are not the policy-makers for their agencies – were Wes Girling (MCPS), Eric Wallmark (County Government), Jan Lahr-Prock (M-NCPPC), Lynda von Barga and Karen Bass (Montgomery College), and Mike Glass and Karen Gerald (WSSC). The union representatives on the committee were Gino Renne and Robert Stewart (MCGEO/UFCW Local 1994), Tom Israel (MCEA), Dave Rodich (SEIU Local 500), John Sparks (IAFF Local 1664), and Walt Bader (FOP Lodge 35). Other participants were: Chuck Milligan, Vice President of the Lewin Group and former New Mexico Medicaid Director; currently Executive Director of the Center for Health Planning, Development and Management, at the University of Maryland, Baltimore County; Wayne Sauseda, Chair of the Commission on Health; and the Confidential Aides of several Councilmembers.

It is important to note that the agreements that have been negotiated recently with MCEA, SEIU, MCGEO, and FOP all contain language that would allow the inclusion of a Canadian drug importation program as part of the prescription benefits package.

To conduct its review the Committee examined extensive information on prescription drugs from Canada, including actions taken or contemplated by states and localities elsewhere, statements by the Food and Drug Administration, and the perspectives of such groups as the Biotechnology Industry Organization and the BioAlliance. All Councilmembers received the Committee's extensive packet of background information dated January 7.

It is important to outline the scope of a potential importation program. The Committee has been studying the feasibility of allowing current and retired employees to import certain maintenance drugs for personal use. Maintenance drugs are medications that people use for long periods of time, such as cholesterol and high blood pressure drugs. Acute care needs and short-term medications would continue to be met at local pharmacies.

The Committee focused on three questions about possible drug importation from Canada:

- Is it safe?
- Is it legal?
- Is it cost-effective?

To help answer these questions, the Committee convened a public forum on February 23. The forum, moderated by Mr. Perez, featured an overview by the benefits experts of prescription drug costs for both agencies and employees; an expert panel with diverse perspectives on the safety, legal, and cost issues; and a panel of employees with concerns about prescription drugs. Testimony offered at the forum is posted on the Council's web site. Panel members included:

**John Rich**, M.D., Medical Director, Boston Public Health Commission  
**William Hubbard**, Senior Associate Commissioner, FDA  
**Dr. John Holaday**, Chairman, Maryland BioAlliance  
**David Nexon**, Senior Health Advisor to Sen. Edward Kennedy, Minority Staff Director for Health Policy for the Senate Committee on Health, Education, Labor and Pensions  
**Stan Gordon**, Second Vice-President, Maryland-D.C Chapter of the Alliance for Retired Americans  
**G. Anthony Howard**, President, CanaRx Services, Inc. Windsor, Ontario  
**Charles Milligan**, J.D., M.P.H., then Vice-President, Lewin Group.

The Committee also developed a survey instrument to which nearly 400 agency employees have already responded. One purpose of the survey was to gauge employee interest in a drug importation program. The initial response to the Committee's survey [396 employees] indicates that 68% of respondents would use the service, 10% would not because they do not use maintenance drugs, and 20% would not use the service. More than 70% of respondents indicated that they believe the County should offer a Canadian mail order option. The full survey is at circles 5-8. When further responses are in hand, the results will be assessed and reported to the Management and Fiscal Policy Committee.

## **2. Prescription Drug Costs for Montgomery County**

The benefits experts' presentation at the Committee's February 23 public forum provided valuable information about prescription drugs costs for the five County and bi-County agencies and their employees. (See circles 9-19.)

More than 40,000 active and retired employees, and their more than 45,000 qualified dependents, receive health benefits. Agencies and employees combined spent more than \$330 million for these benefits in 2003. Of this total, prescription drugs cost an estimated \$70 million.

Specific data on prescription drug costs is sometimes difficult to extract, particularly when drug coverage is not stand-alone – as, for example, in the Kaiser plan. MCPS and M-NCPPC provide stand-alone programs where the cost is more easily captured.

MCPS' experience is representative of all agencies' experience. Between 1997 and 2003:

- Prescription drug costs more than doubled for active employees (from \$883 to \$1,992) and nearly doubled for retirees (from \$1,513 to \$2,913).
- The average net drug cost per script rose sharply for both active employees (from \$37.68 to \$71.09) and retirees (from \$47.24 to \$67.15).
- The average number of scripts rose, although somewhat less sharply, for both active employees (from 23.4 to 28.0) and retirees (from 32.0 to 43.4).

These statistics are consistent with the national trends. Families USA, a group that tracks healthcare issues for consumers, reports that the prices for the 50 top selling drugs have increased at rates that are 'significant multiples of inflation' for more than a decade. "From January 2002 to January 2003, for example, the prices of those top 50 drugs rose by almost three-and-one-half times the rate of inflation."

[[http://www.familiesusa.org/site/PageServer?pagename=medicare\\_drug\\_discount\\_card](http://www.familiesusa.org/site/PageServer?pagename=medicare_drug_discount_card)]

### 3. Other Jurisdictions with Current or Potential Prescription Drug Importation Programs

The number of states and localities that have expressed interest in importation programs has grown rapidly over the last year, and the landscape continues to change rapidly. **Springfield, Massachusetts** and **Montgomery, Alabama** actually started limited programs for their employees and retirees in 2003. Springfield raised co-payments for domestic drugs and waived them for imported drugs. The results from December 2003, shown on circle 20, indicate that 31% of the 10,031 eligible employees have enrolled. Savings on 2,434 prescriptions issued in December were \$243,605 or 40.7%. A column on circles 21-23 by former Mayor Michael Albano, who started the program, provides further details. **Boston**, whose Medical Director participated in the Committee's February 23 public forum, is carefully planning to implement a program later this year. The following cities have requested proposals for a program from the same Canadian pharmacy benefits manager as Springfield: New Castle, DE; Fort Wayne, IN; Seattle, WA; Quincy, MA; and Schenectady, NY.

Many states have expressed interest. **Illinois** issued an extensive report in October 2003 that posited large savings, but when the federal waiver it requested to implement the program was not granted, it did not proceed. **Vermont** has also sought a federal waiver.

Other states have taken more direct action. **Minnesota** has a website that lists pharmacies that the state has inspected and certified. **Wisconsin** has created a web site linking residents to Canadian pharmacies that provide specific safeguards. Pages from these websites start at circle 24. **New Hampshire** has created a similar website but has not taken it live at this time. **Iowa** and **West Virginia** are among the other states contemplating action. There is a bill pending in the Maryland Senate that would allow importation of Canadian drugs for state employees.

#### 4. Federal Political Context

Before reviewing the key safety, legal, and cost issues associated with drug importation, we believe that a sense of the federal political context would be useful. Part of this context is the debate between the FDA and its critics over legal issues, which are discussed below. Another part is the growing bipartisan focus on this issue in Congress, parallel to the state and local focus.

In September 2003 the House of Representatives, by a vote of 243-186, approved legislation directing the Department of Health and Human Services to establish a system for importation of FDA-approved drugs from FDA-approved facilities in Canada, the European Union, and seven other nations. A bipartisan group of Senators introduced a similar bill in the Senate, but the final Medicare prescription drug bill in late 2003 included a much more limited provision on drug importation, as noted below.

So far in 2004, the landscape has continued to change. AARP, which helped to pass the Medicare prescription drug bill, has intensified its support for importation. While there remains opposition to importation, some former opponents, such as Republican Senators Trent Lott and John Cornyn, have recently changed their position to support it, as Senator Edward Kennedy and others did last year.

Recently Senators John McCain and Byron Dorgan temporarily held up the nomination of FDA Commissioner Mark McClellan to head the Medicare and Medicaid programs because of his position on importation. Senator William Frist has agreed to allow a drug importation bill to come to a vote in the Senate this year. Passage of the measure now appears likely in the Senate, although whether it will become law again remains far from certain.

#### 5. Safety Issues

The primary goal of Montgomery County's employee health benefits programs is the well-being of participants. Any prescription drug program must ensure safe and easy access to the drugs prescribed by an employee/retiree's physician. The key question is: can one design a safe and reliable program for importing drugs from Canada?

The Committee spent considerable time addressing this issue and reviewed a host of documents and reports. It received technical assistance from a high ranking official from the Lewin Group (a national healthcare consulting firm). It received testimony from a variety of witnesses at the public forum, including a senior associate commissioner from FDA and the medical director for Boston's public health system. The Committee also met with the senior management team of the Canadian company that is working with Springfield, Massachusetts and other government entities to implement these programs.

#### **A. Conflicting Stands**

The Food and Drug Administration maintains that it is unsafe to import drugs from Canada or any other country. In testimony before the Committee on Government Reform's Subcommittee on Human Rights and Wellness (June 12, 2003), Senior Associate Commissioner William K. Hubbard, stated the Administration's position on the safety of importing prescription drugs from Canada:

For public health reasons, FDA remains concerned about the importation of prescription drugs into the U.S. In our experience, many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. FDA cannot assure the American public that drugs imported from foreign countries are the same as products approved by FDA.

FDA has long taken the position that consumers are exposed to a number of risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies licensed under state pharmacy law.

In response to a question by Rep. Dan Burton (R-IN) at the same hearing, Commissioner Hubbard stated that FDA has no record of any harm to any person who has imported drugs from Canada. IMS Health, Inc., which tracks prescriptions for the health industry, estimates that more than 1 million United States residents buy drugs from Canada and have been doing so for years. The Governor of Wisconsin has estimated that 2 million Americans are buying drugs from Canada. Testimony at the Committee's public forum noted that 8 million prescriptions were filled in Canada for Americans in 2003. The FDA has not provided any incident of an American consumer being harmed by prescription drugs from Canada.

The City of Springfield, Massachusetts has had a Canadian drug importation program for employees in place since July 2003. The program is voluntary, and approximately one-third of eligible employees (3,112) have enrolled. They order their maintenance drugs from CanaRx, Inc. and the City pays the bill as part of the employee benefits package. CanaRx, Inc. is a pharmacy benefits manager (PBM) that contracts with Canadian pharmacies to fill prescriptions written in the USA. The City does not import, order, or possess the drugs at any point in the process. A description of the process is on circles 29 and 30. In December 2003, 2,434 prescriptions were filled at a 40% savings

(\$243,605) when compared to retail pharmacy costs in the USA. After six months there are no reports of any safety problems for Springfield employees.

### **B. Can We Design a Safe Importation Program?**

Numerous organizations have concluded that importation programs can be safely designed. The U.S. Congress has passed laws (e.g., MEDS Act of 2000, Medicare Modernization Act of 2003) establishing guidelines for creating safe importation programs.

A major report by the State of Illinois concluded last year that:

- Employees and retirees can purchase safe and lower cost drugs from Canada.
- Pharmacy practice in Canada is equal or superior to the pharmacy practice in the State of Illinois
- Several features of the proposed plan designs for State of Illinois employees and retirees could encourage increased patient safety...
- The Canadian regulatory system provides substantially equivalent protection for the health and safety of the public as is provided in the State of Illinois. While there are differences in details of how the pharmacy profession is regulated, the standards of safety and efficacy of prescription drugs are comparable.
- Currently the Canadian system for pricing and distribution of pharmaceuticals is less likely than that of the system in the United States to foster drug counterfeiting...
- The United States and Canada have comparable requirements at virtually every level for the warehousing and storage of pharmaceuticals.

Report On Feasibility of Employees and Retirees Purchasing Prescription Drugs in Canada, Oct. 27, 2003, Illinois Department of Central Management Services  
<http://www.affordabledrugs.il.gov/pdf/SpecialAdvocateCanadian10-27-03Final.pdf>

Charles Milligan, Vice-President of the Lewin Group and former Medicaid Director for New Mexico, reported to the Committee that in his judgment it is possible to design a safe program for importing drugs from Canada (circle 31-34). Mr. Milligan noted that it would be important to conduct a significant amount of due diligence before putting a program in place. He outlined a series of measures that he believes would ensure the safety of any program, and noted that they would be consistent with all of the Canadian drug reimportation guidelines signed into law by President Bush in December 2003 as part of the Medicare Modernization Act (H.R.1). These safety measures are:

- Only FDA-approved medications;
- Maximum 90-day supply of any given medication (to discourage re-sale, and allow for regular monitoring);
- Prohibit importation for the "first fill" of any given medication (to establish it is effective and tolerated by the patient);

- Permit importation only of County-designated maintenance medications for chronic conditions;
- The prescription must be written by the participant's local treating physician;
- The County should carefully select the approved Canadian vendor(s) according to criteria such as on-site physicians, 24 hour call center staff, and a record of compliance with all Canadian licensure laws;
- The Canadian vendor(s) must register with the Secretary of the federal Department of Health and Human Services ("HHS");
- The prescription must be for personal use by the County plan participant, and not for resale; and
- The prescription must be in the form of a final finished dosage that was manufactured in an establishment registered with the FDA.

The Committee continues to search for evidence that Americans who import prescription drugs from Canada, or Canadians who purchase prescription drugs, have encountered safety problems. It appears that the widespread practice of importing prescription drugs from Canada that currently exists has created no significant public health problem in America.

In the public forum, Dr. John Holaday, Chairman of the Maryland BioAlliance, raised a number of specific safety concerns pertaining to importation of biotech drugs. The Committee agrees that biomed, because of their unique properties and storage requirements, present particular concerns, and that it would be inappropriate to permit importation of biomed. Thus, if the County were to adopt a drug importation program, the Committee recommends that biomed not be included in the list of maintenance drugs eligible to be purchased from Canada.

## **6. Legal Issues**

There are two legal questions surrounding the drug importation proposal. First, does it violate federal law, specifically, the Food, Drug and Cosmetic Act? Second, what are the tort liability implications for the County?

### **A. Does the Proposed Drug Importation Proposal Violate Federal Law?**

There is considerable disagreement as to whether a voluntary drug importation program would violate federal law. The FDA says unequivocally that such programs violate the Food, Drug and Cosmetic Act. (FDCA). In an August 25, 2003 letter to the Attorney General of California (<http://www.fda.gov/opacom/gonot.html>), the FDA opined that:

...virtually all drugs imported to the United States from Canada violate the FDCA because they are unapproved (21 U.S.C. § 355), labeled incorrectly (21 U.S.C. §§ 352, 353), or dispensed without a valid prescription (21 U.S.C. § 353(b)(1)). Importing a

drug into the United States that is unapproved and/or does not comply with the labeling requirements in the FDCA is prohibited under 21 U.S.C. §§ 331(a), and/or (d).

FDA approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. Generally, drugs sold outside of the United States are not manufactured by a firm that has FDA approval for that drug. Moreover, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the United States approval, and thus it is considered to be unapproved. 21 U.S.C. § 355. The version also may be misbranded because it may lack certain information that is required under 21 U.S.C. §§ 352 or 352(b)(2) but is not required in the foreign country, or it may be labeled in a language other than English (see 21 C.F.R. § 201.15(c)).

Second, with respect to "American goods returned," it is illegal for any person other than the original manufacturer of a drug to import into the United States a prescription drug that was originally manufactured in the United States and sent abroad (21 U.S.C. § 381(d)(1)). This is true even if the drug at issue were to comply in all other respects with the FDCA. *Id.* Importing a drug into the United States in violation of section 381(d)(1) is prohibited under 21 U.S.C. § 331(t).

There is an opinion from an Assistant Attorney General of Maryland agreeing with the FDA's analysis. (See circles 35-39).

However, there are others who disagree with the FDA's analysis. The Attorney General of Minnesota has concluded that it is possible to implement a drug importation program without running afoul of the FDCA. In a letter dated October 2, 2003, the Attorney General made the following statements:

Under current law, the federal Food, Drug and Cosmetic Act prohibits the importation of drugs into the United States from Canada by anyone other than a drug manufacturer if the drugs were manufactured in the United States. See 21 USC 381(d)(1). This provision of the law has been tempered by the FDA's longstanding practice of allowing consumers to import small amounts of prescription drugs for their own personal use. Additionally, Section 381(d)'s prohibition may be lifted if the Secretary of Health and Human Services certifies the safety of such drugs being imported. See 21 U.S.C. 384(l). To date, the Secretary has refused to do so even though drugs have been imported from Canada for years and the FDA

has acknowledged that there have been no or negligible safety problems associated with these imported drugs....

There is, on the other hand, no legal prohibition on the importation of drugs from Canada which are manufactured in other countries if the drugs are FDA approved, properly labeled and prescribed by a physician. See 21 U.S.C. 353, 355. *Accordingly, it is our opinion, that under current law, the State could implement a program regarding those medications either by buying direct or by establishing a conduit through which Medicaid recipients could purchase such medication.* [Emphasis added] (See circles 40-43 for full letter).

Minnesota and Wisconsin have set up web sites for their residents that contain information about how to purchase prescription drugs from Canada. Public health officials from both states traveled to Canada to investigate and identify pharmacies that had programs and practices in place that satisfied safety requirements. As a result, they identified recommended Canadian pharmacies for residents seeking to purchase prescription drugs from Canada. The web sites also provide a series of helpful safety tips for residents seeking to purchase prescription drugs from Canada. The FDA contends that these websites violate the FDCA, but has taken no action to stop these states from providing this information to interested parties. Officials from Wisconsin and Minnesota believe that these web sites, which merely provide information so that people can make informed decisions, do not run afoul of the FDCA.

The FDCA is not the only federal statute relevant to this analysis. In 2000, Congress weighed in on the importation debate when it passed the so-called MEDS Act of 2000. This bill, which was signed by President Clinton, allowed American consumers, pharmacists, and wholesalers to purchase FDA-approved prescription drugs on the international market, including Canada. The bill directed FDA to implement the law, but FDA has declined to do so, claiming that it cannot assure the safety of the products being shipped into the United States. Thus, the MEDS Act, which reflected an effort to clarify the status of drug importation, was never implemented.

In a 2003 hearing in the United States House of Representatives on a proposal to allow for drug importation from Canada, Congressman Dan Burton, Chair of the Committee, made the following statement in response to claims by FDA Associate Commissioner William Hubbard that virtually all drugs imported to the United States from Canada by or for individual U.S. consumers violate the FDCA.

I, for one, am puzzled [by this claim]. How can the FDA officials feel that Americans are violating U.S. law when three years ago the President [Clinton] signed into law a bill [the MEDS Act] that Congress had passed? This bill clarified that it was legal for Americans to purchase prescription drugs internationally.

We are a country with three branches of government- Judicial, Executive and Legislative. It is not the FDA's job to make the laws. It is their responsibility to implement the laws that Congress passes. And that includes the MEDS Act. So far, FDA has shirked its responsibility in this area.

Congressman Burton raised a host of questions about whether the FDA's position that drug importation from Canada was illegal was accurate.

Charles Milligan, J.D., M.P.H., the former Medicaid Director of New Mexico and Vice President of the Lewin Group, a national health care consulting group in Virginia, provided technical assistance to the working group. As noted earlier, Mr. Milligan outlined a series of steps that the County could take to ensure a safe and effective program. In addition, Mr. Milligan, a former practicing health law attorney, noted that in his view, the legal landscape is "muddy." Milligan outlined a series of legal arguments that could be made to support the claim that importation of drugs from Canada is legal. He concludes by observing that "the legal issues are unresolved, and are certainly not as clear cut as the FDA would suggest." His letter appears at circle 31-34.

Another factor that muddies the legal waters further is the potential application of the North American Free Trade Agreement (NAFTA). A number of questions have arisen as to whether an importation ban would violate specific provisions of NAFTA. Serious questions have been raised as to whether the FDA's position opposing importation is based on scientific principles or an appropriate risk assessment.<sup>1</sup> If the FDA's actions are deemed arbitrary and capricious, these actions may constitute a disguised restriction on trade within the meaning of Article 712 of NAFTA.

In addition, if less trade-restrictive means exist for addressing any legitimate health or safety concerns (such as a program contemplated in the importation bill that passed the House of Representatives in 2003, or the program outlined in the MEDS Act of 2000, which was signed into law by President Clinton but never enforced by the FDA), an outright ban on importation may also constitute an unnecessary obstacle to trade under NAFTA Articles 712 and 904.

Finally, Article 301 of NAFTA requires that the United States grant "national treatment" to the goods of Canada. This provision is meant to capture the special relationship between the two countries, and the mutual confidence that the two countries have in each other's products. There is a private right of action for violations of NAFTA, although it does not appear that the County would have this private right of action. Instead, the Canadian company that was prevented from doing business in the United States would have standing to file a NAFTA claim against the United States. The NAFTA

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<sup>1</sup> As noted earlier, 8 million prescriptions were filled in Canada in 2003 by Americans, amounting to roughly \$1 billion in business. Americans have been purchasing prescription drugs from Canada for years, with no apparent ill effects. As a result, many stakeholders, including but not limited to members of Congress, are questioning whether the ban is a result of scientific analysis, or is arbitrary and capricious.

claims are by no means clear cut. It is conceivable that these provisions of NAFTA would not apply. An international tribunal would make this judgment.

Overall, the existence of NAFTA adds another layer of legal complexity to the overall analysis.

### **B. Tort Liability Implications for the County**

Potential tort liability is an additional legal issue that must be considered in making the determination as to whether to implement a voluntary program of drug importation for current and retired employees. In an August 25, 2003 letter to the Deputy Attorney General of California, the FDA remarked that the state of California could be potentially liable in tort if a California citizen were injured by a drug that the state purchased in violation of federal law, but noted it had not researched, nor did it have any advice, on the issue. Moreover, the opinion did not discuss the issue of whether a municipality may be immune from suit under principles of sovereign immunity. A former Department of Justice attorney, writing in a recent issue of the Legal Times (March 1, 2004), opined that municipalities who put drug importation programs in place confront potential tort liability. No filings or case law were cited to show that such theories would ultimately be successful.

As noted above, there were 8 million prescriptions filled in Canada for Americans last year for a total of roughly \$1 billion in business. While the Committee continues to search, we are unaware of any tort cases that have been filed by Americans arising out of the importation of drugs from Canada. At the public forum, Mr. Stan Gordon, representing an organization that runs buses to Canada, reported very high marks from users. Nonetheless, it is still necessary to look at tort liability issues because it only takes one negative incident to trigger a lawsuit.

From a tort liability perspective, it would be important to investigate whether the County would have potential immunity from suit under principles of sovereign immunity. Two additional keys to minimizing exposure are to (1) ensure that significant due diligence is performed before a program is put into place so that safety is certain; and (2) draft a disclaimer that will ensure that the users understand the risks of the program, understand that it is voluntary, and agree to participate.

One may question whether it is possible to draft a disclaimer in this context. There is a Maryland Court of Special Appeals case that speaks to the validity of disclaimers. One question is whether such a waiver would be deemed contrary to public policy. In *Seigneur v. National Fitness Institute, Inc.*, 132 Md. App. 271 (Md. App. 2000), the Maryland Court of Special Appeals affirmed a health club's summary judgment motion finding that an exculpatory clause signed by a former member expressed a clear intent to release the health club from all acts of negligence. The Court rejected plaintiff's argument that the health club provided an essential public service such that the exculpatory clause would be "patently offensive" to citizens of Maryland.

In its opinion, the court identified exceptions where the public interest will render an exculpatory clause unenforceable, specifically where i) the bargaining power of one party to the contract is so grossly unequal so as to put that party at the mercy of the other's negligence; and ii) when the transaction involves the public interest. The court explained that one party has decisive bargaining power over the other party when the service offered is "of great importance to the public", "essential in nature", and is considered "a practical necessity for some members of the public." *See id.* at 283-84.

Facilitating the purchase of prescription drugs could be considered all of these things. However, the court stated that the ultimate determination of what constitutes the public interest must be made considering the "totality of the circumstances of any given case against the backdrop of current societal expectations." *Id.* at 287. The court went on to identify transactions affecting public interest as those involving the performance of a public service obligation, including transactions "that are so important to the public good that an exculpatory clause would be 'patently offensive,' such that 'the common sense of the entire community...would pronounce it invalid.'" *Id.* at 287.

In this instance, factors that would support the validity of such a disclaimer include the uniformly positive experiences of millions of Americans who import drugs from Canada, the careful thought that would go into a County program, and the fact that it is voluntary. No person has to participate. Anyone who wants to continue purchasing prescription drugs from the United States will be able to do so.

As noted above, Wisconsin and Minnesota have established web sites to assist people who want to purchase prescription drugs from Canada. These web sites contain lengthy notices and disclaimers that may be useful if the County chooses to go forward with a program. It may be useful to touch base with other municipalities that have programs in place to determine whether what disclaimers they are using.

Overall, from a tort liability perspective, if a program were to be implemented, it would be important to craft a careful disclaimer, and to perform the necessary due diligence so that the program is unquestionably safe.

### **C. Overall Legal Picture**

While the legal landscape is muddled, both domestically and under NAFTA, a few things are clear. Nobody who purchases drugs from Canada for personal use has ever been sued by the FDA. Their practice has been not to take action against individuals who import drugs for personal use. Thus, people who choose to participate in this program will not be sued by the FDA.

In addition, although Springfield, Massachusetts, and Montgomery, Alabama have had programs in place for months, the FDA has not sued them, and has not sued any other municipality or government entity that has a program in place. In fact, the Boston Globe has reported that Associate Commissioner William Hubbard told a state legislative panel in Massachusetts that the FDA does not intend to take action against Springfield. In this same article, Commissioner Hubbard was quoted as stating that enforcement would be

directed towards "businesses that sell commercial quantities of drugs" from overseas and that the FDA was "not considering legal action against cities or states." [*FDA Eases Stance on Importing Medicines*, *Boston Globe*, 10/24/2003 Circle 44]. At the recent public forum, Commissioner Hubbard, when asked about this article, indicated that this was not precisely what he said. However, the article appeared in October 2003, after the Springfield program had been in place for months. As of today, no lawsuit has been filed against Springfield or any other municipality. As Commissioner Hubbard noted at the forum, "There is a question as to whether FDA would take action against any given individual or entity." He later clarified further the FDA's position: "We certainly would sue another public official with great reluctance...The good guys shouldn't be fighting the good guys."

In the importation context, the cases that the FDA has litigated have all been against American based intermediaries who were middle people in drug importation programs. In those cases, the FDA filed an action under the FDCA seeking an injunction for the company to cease and desist its actions. If a lawsuit were filed against Montgomery County, it is fairly clear that it would closely resemble the lawsuits filed against the intermediaries. Commissioner Hubbard essentially acknowledged this in the recent forum. Thus, as a practical matter, the most plausible "worst case" scenario for the County, in fact, the only plausible scenario is a federal lawsuit seeking an injunction directing the County to terminate the program.

The Bush Administration is a strong supporter of free trade generally, and the North American Free Trade Agreement in particular. The inconsistency between Administration support for NAFTA on the one hand, and efforts to restrict importation of drugs from Canada, may explain in part the federal government's reluctance to sue municipalities and to take action against Canadian companies such as CanaRx that are working with American municipalities.

Tort liability is a possibility under the County's current program, and would certainly be a possibility under a program of drug importation.

## **7. Cost Issues**

The Committee considered at length what savings can be achieved from a drug importation program. The unions and agencies have worked very hard to implement a host of creative solutions to contain health care costs, including but not limited to studying the feasibility of drug importation. Some of these are listed in circles 45-49.

Two caveats are in order at the outset. First, savings estimates made by other jurisdictions have sometimes assumed that all eligible employees would participate. Since participation would be voluntary, and since employees would have many questions at the outset and perhaps thereafter, assumptions about participation rates must be realistic. One real world indicator is the experience of Springfield, Massachusetts, which reported a 31% participation rate in December 2003.

Second, at some point prices will be affected by the law of supply and demand, particularly if large employers, as opposed to individuals alone, become important players in drug importation. Some drug companies, for their part, have already started to restrict exports to Canada, although questions have been raised as to whether these drug companies are violating antitrust laws.

That said, savings can still be considerable. For example, the graphs on circles 17 and 18 prepared by Wes Girling suggest that under a full participation scenario, MCPS could save \$400,000 on Lipitor purchases and \$500,000 on Prevacid purchases alone.

Another cost analysis appears in the testimony delivered by MCEA President Bonnie Cullison at the Committee's February 23 public forum. (See circles 50-56.) The analysis estimates savings for all agencies combined at \$14.9 million if all eligible employees participate. The analysis also estimates that more realistic participation rates of 25% and 40% would still produce savings of between \$3.7 and \$6.0 million.

#### **8. Other Ways to Maintain Benefits and Control Costs**

As this Committee pursued issues related to drug importation, we discussed other important initiatives that we commend to the Management and Fiscal Policy Committee and the full Council for further review. These initiatives can help to control costs, and controlling costs – as several of our union participants in particular pointed out – is essential to maintaining benefits rather than reducing them, as so many employers elsewhere have done.

One initiative, as recommended last year by the Holloway Task Force and the MFP Committee, is to accelerate joint procurements of health insurance. All of the new strategies examined by the Holloway Task Force can be found at circle 57. The agencies' limited joint procurements to date have worked well, and with a still larger pool there can be additional economies of scale. We noted that agencies now pay often different prices for prescription drugs. It is wasteful that the cost to the County of Lipitor depends on which agency is purchasing the drug. All agencies should be able to achieve the lowest possible prices.

Other initiatives we discussed are summarized well in MCEA President Bonnie Cullison's testimony. Agencies should:

- Encourage the use of generic over brand name drugs when available. For example, while a 30-day supply of 20 mg of Prozac costs \$165, its generic equivalent, Fluoxetine, costs just \$63, or 62% less.
- Encourage mail-order purchases of maintenance drugs. For example, a 90-day supply of 10 mg of Lipitor costs \$230 retail but just \$165 mail-order, or 28% less.

Agencies now differ widely in their employees' use of mail-order. M-NCPPC has sharply increased use of mail-order by providing a strong financial incentive illustrated in

the table on circle 58. MCPS now requires retirees to use mail order for maintenance drugs. Real cost savings can be achieved through expanded use of mail order.

- Incorporate drug formularies into prescription plans to promote effective treatments at the most affordable price.

- Purchase expensive biotech drugs directly from the manufacturer via specialty pharmacies.

- Expand the use of prescription discount cards. For example, the Office of Human Resources has just announced that effective April 1, 2004 County Government indemnity plan participants can use a Caremark discount card to purchase drugs at over 55,000 participating pharmacies nationwide. Discounts are about 15% for prescription drugs and as much as 50% for generic drugs.

#### **9. Strategies for Reducing Drug Costs for County Residents At Large**

During the course of the Committee's review, we frequently received inquiries from County residents as to whether they could participate in the County's drug importation program, if one were put in place. Although the plan under study is limited to County employees and retirees, we did identify at least one program that may be beneficial to residents without prescription drug benefits, and cost the County nothing. It may be possible to set up a prescription drug discount card program for residents. It would have savings similar to those mentioned above—a 15% discount for prescription drugs and up to a 50% discount for generic drugs. This simply involves the County leveraging its purchasing power to benefit not only employees, but any resident of the County.

Many residents already have health plans that cover prescription drugs, and therefore would not benefit from participation. However, many residents, especially the more vulnerable who have no or minimal health coverage, are paying full retail price for their prescriptions. This program would enable them to get a discount on their drugs. There is no substitute for meaningful reform at the federal level. However, until such reform occurs, this program may help many people in need and merits further review.

Residents are also able to use the Minnesota or Wisconsin websites that have been operating for a number of months without any detrimental outcome.

<http://www.state.mn.us/cgi-bin/portal/mn/jsp/home.do?agency=Rx>  
<http://www.drugsavings.wi.gov/>

#### **10. Findings and Recommendations**

The Committee concludes that a voluntary program that allows employees, retirees, and their dependents to order maintenance drugs from an approved Canadian supplier makes sense.

#### **A. Is It Safe?**

**The Committee concludes that a program can be developed that would ensure the safety of participants.** It would require considerable due diligence and input from public health professionals, but it has been done elsewhere in the US and can be done here.

The program should include only maintenance drugs. It should not include biomed. A group of benefits managers, public health officials, and consultants should take up the task of devising a program that takes into consideration the following elements:

- Only FDA-approved medications;
- Maximum 90-day supply of any given medication (to discourage re-sale, and allow for regular monitoring);
- Prohibit importation for the "first fill" of any given medication (to establish it is effective and tolerated by the patient);
- Permit importation only of County-designated maintenance medications for chronic conditions;
- The prescription must be written by the employee's local treating physician;
- The County should carefully select the approved Canadian vendor(s) according to criteria such as on-site physicians, 24 hour call center staff, and a record of compliance with all Canadian licensure laws;
- The Canadian vendor(s) must register with the Secretary of the federal Department of Health and Human Services ("HHS");
- The prescription must be for personal use by the County plan participant, and not for resale; and
- The prescription must be in the form of a final finished dosage that was manufactured in an establishment registered with the FDA.

#### **B. Is It Legal?**

**The Committee concludes that while there is some risk of litigation due to the muddled legal picture, the risk of actual litigation is low.** The FDA has not taken action against any municipality, and it appears clear that the most likely action, if any, would be a civil suit for injunctive relief (e.g., cease and desist). There are a host of potentially viable defenses that can be raised in the unlikely event of litigation by the federal government. There should be further discussion with the County Attorney about the civil and criminal provisions of the Food, Drug and Cosmetics Act, as well as potential tort liability.

#### **C. Is It Cost-Effective?**

**The Committee concludes that Montgomery County could save millions of dollars in prescription drug costs by implementing a voluntary Canadian drug importation program for employees and retirees.** These savings could reach as high as \$6 million per year with 40 percent participation. Participation in the voluntary program is the primary variable that affects the amount of money saved. If most or all employees participated, the savings could reach \$15 million per year. If there is a way to capture

savings for employees that currently use health plans that embed prescription costs, the savings would increase.

#### **D. Are There Other Important Strategies?**

The Committee concludes that there are considerable potential savings in restructuring the current disparate prescription benefits programs into a single program that takes advantage of economies of scale. There are also important cost-saving strategies involving generic drugs and mail order for maintenance drugs. The MFP Committee and the County benefits managers should pursue all of these strategies assiduously. However, the programs should be subject to negotiation, and no program should be put in place unless it has been the subject of collective bargaining.

The Committee concludes that the potential inclusion of County residents in drug discount programs should be examined. The health and economic benefits for residents without insurance or drug benefits could be considerable.

#### **E. Recommendations**

The Committee recommends that Montgomery County:

1. Design a health benefits program for employees and retirees that includes the option of safely ordering FDA approved prescription drugs from Canada at significantly reduced cost. The program should be limited to certain maintenance drugs, and should exclude bio-medications. The program should increase incentives for the use of any domestic or Canadian mail order option.
2. Restructure existing health benefits to take advantage of economies of scale that can reduce overall costs to the County and employees and retirees.
3. Investigate fully the potential for establishing a prescription drug benefits program for County residents.

#### **11. Next Steps**

The Committee believes that the following steps should be taken as soon as possible to implement the recommendations.

1. A working group should be convened, composed of representatives of interested unions, benefits managers, public health officials, and other experts as needed, to begin the due diligence necessary to put a voluntary drug importation program in place.
2. Requests for Interest or Proposal for prescription benefits programs with a Canadian mail order option should be issued as part of the current contract cycle to get final estimates on costs and program elements.
3. Consultation with the County Attorney on the provisions of the Food, Drug and Cosmetics Act, and other legal issues should be initiated.

4. Requests for Interest or Proposal for a prescription drug discount benefit that could be made available to County residents should be issued.